Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Detrusitol 2 mg film-coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each filmcoated tablet contains tolterodine tartrate 2 mg corresponding to 1.37 mg tolterodine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from Austria:
The film-coated tablets are white, round and biconvex. The tablet is engraved with arcs above and below the letters DT.

4 CLINICAL PARTICULARS

As per PA0019/072/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0019/072/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Cellulose, microcrystalline
Calcium hydrogen phosphate dihydrate
Sodium starch glycollate (Type B)
Magnesium stearate
Colloidal anhydrous silica

Film coating:

Coating granules containing
Hypromellose
Cellulose, microcrystalline
Stearic acid
Titanium dioxide E171

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on

the market in the country of origin.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Tablets are packed in blister package made of PVC/PVDC and aluminium foil with a heat seal coating of PVDC.

Pack size: 56 film-coated tablets (4 x 14)

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18,
Oxleasow Road,
East Moons Moat,
Redditich,
Worcestershire B98 ORE,
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/060/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th December 2014.

10 DATE OF REVISION OF THE TEXT